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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/866,557	05/24/2001	Scott Hammond	CSHL-P02-010	4804

28120 7590 09/06/2006

FISH & NEAVE IP GROUP
ROPES & GRAY LLP
ONE INTERNATIONAL PLACE
BOSTON, MA 02110-2624

EXAMINER	
MCGARRY, SEAN	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 09/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/866,557	HAMMOND ET AL.	
	Examiner	Art Unit	
	Sean R. McGarry	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,9,10,12,14,15,28,47 and 48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,9,10,12,14,15,28,47 and 48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/12/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application was withdrawn from issue due to a mistake by the office. See the NOTICE OF WITHDRAWAL FROM ISSUE UNDER 37 CFR 1.313(b) mailed 4/10/06.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/11/05 has been entered. This is the first action on the merits after the filing of the above RCE in view of the above withdrawal from issue.

This action corrects the mistake of the Office and makes new grounds of rejection. Applicants arguments filed 8/11/05 are moot in view of the new rejections made below.

Applicant filed a declaration under 37 CFR 1.131 that was considered by the examiner of record at that time. The declaration is defective and cannot be relied upon to antedate a reference. The declaration is signed only by Gregory Hannon where Gregory Hannon is not identified as **THE** inventor of the rejected claims. The declaration describes him as **AN** inventor. "The inventor of the subject matter" is interpreted to

mean the inventive entity that has invented the claimed subject matter. The instant application names Gregory Hannon and Scott Hammond as the individuals that are the inventors of the invention claimed (see petition filed under 37 CFR 1.148(b) on 12/17/2004). The context of the MPEP does not indicate that it is sufficient for **an** inventor to file a declaration to antedate a reference.

The relevant parts of the MPEP are reproduced below:

MPEP 715 [R-3] Swearing Back of Reference — Affidavit or Declaration Under 37 CFR 1.131

37 CFR 1.131. Affidavit or declaration of prior invention.

(a) When any claim of an application or a patent under reexamination is rejected, the inventor of the subject matter of the rejected claim, the owner of the patent under reexamination, or the party qualified under § § 1.42, 1.43, or 1.47, may submit an appropriate oath or declaration to establish invention of the subject matter of the rejected claim prior to the effective date of the reference or activity on which the rejection is based. The effective date of a U.S. patent, U.S. patent application publication, or international application publication under PCT Article 21(2) is the earlier of its publication date or date that it is effective as a reference under 35 U.S.C. 102(e). Prior invention may not be established under this section in any country other than the United States, a NAFTA country, or a WTO member country. Prior invention may not be established under this section before December 8, 1993, in a NAFTA country other than the United States, or before January 1, 1996, in a WTO member country other than a NAFTA country. Prior invention may not be established under this section if either:

It should be noted, however, that the examiner has looked at the declaration and offers the following if applicant intends to perfect or refile the declaration. The declaration, as it pertains to the invention now claimed, would lack convincing or sufficient evidence such that prior possession would be shown. The declaration and accompanying exhibits fails to show a hairpin expressed from a vector. The declaration and exhibits fail to show inhibition in cells where an shRNA is expressed from a vector. The declaration and exhibits fail to show mammalian cells in culture. Exhibit D appears to be a black box with a small inset of "Redacted" set therein. Exhibit D provides no meaningful evidence as it appears in the IFW.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 recites the limitation, wherein expression of the target gene is attenuated by at least 5 fold. It is unclear what one in the art would use as the basis for the 5-fold reduction. For example one could assume various standards to make such a comparison. It is unclear what one in the art would be required to compare the required 5 fold reduction to. In the context of the instant claim 5-fold would be considered a

relative term since the claim does not provide a basis for a comparison, for example. The claim fails to provide a clear metes and bounds

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 9, 10, 12, 14, 15, 28, 47, and 48 are rejected under 35 U.S.C. 102(e) as being anticipated by Fire et al [US 6,506,559].

Fire et al disclose a method to inhibit expression of a target gene in a cell in vitro comprising the introduction of a ribonucleic acid into the cell in an amount sufficient to inhibit expression of the target gene, wherein the RNA is a double-stranded molecule with a first strand consisting essentially of a sequence of he target gene and a second strand consisting essentially of a sequence that is complementary to the nucleotide sequence of the target gene.

The target gene may be a gene derived from the cell or a gene of a pathogen which is present in the cell [column4, line28-30, for example]. The double-stranded RNA structure may be formed by a single self-complementary RNA strand [column 4, lines 41-45; and column 7, lines 42-52, for example]. Inhibition is disclosed as being sequence specific [column 4, lines 50-51, for example]. The cell with the target gene can be derived from mammals such as primates [column 8, lines13-51, for example]. The double stranded RNA can be expressed from a vector [columns 4-5, and column 8, line62- column 9, line25, for example]. It is disclosed that RNA containing sequences that are identical to a portion of the target gene are preferred [see column 7, line53-column 8, line 12, for example]. Fire et al indicate that the level of inhibition is dependent on the dose [column 7, for example].

Fire et al meet all of the structural limitations for the compound required in the instant claims. Any functional limitations such as being a substrate for RNAse III, not producing a general sequence independent killing in mammalian cells (PKR response) and inhibition by at least 5 fold are presumed by the examiner to be present in the structures disclosed by Fire et al since they meet all of the structural requirements of the

claims. If applicant believes that there is/are specific structures that provide for these properties of the claimed method and are not disclosed by the prior art applicant should point to those structures of their claimed invention as they pertain to mammalian cells.

Applicant is reminded:

> **A REFERENCE TEACHING PRODUCT APPEARING TO BE SUBSTANTIALLY IDENTICAL IS MADE THE BASIS OF A REJECTION,**
> **AND THE EXAMINER PRESENTS EVIDENCE OR REASONING TENDING TO SHOW INHERENCY, THE BURDEN SHIFTS TO THE**
> **APPLICANT TO SHOW AN UNOBVIOUS DIFFERENCE**
>
> **"[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency' under 35 U.S.C. 102, on prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. *In re Fitzgerald,* 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting *In re Best,* 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)).**
>
> **MPEP 2112.01:**
>
> **PRODUCT AND APPARATUS CLAIMS X WHEN THE STRUCTURE RECITED IN THE REFERENCE IS SUBSTANTIALLY IDENTICAL TO THAT OF THE CLAIMS, CLAIMED PROPERTIES OR FUNCTIONS ARE PRESUMED TO BE INHERENT**
>
> **Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). AWhen the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.≅ *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433.**

A REJECTION UNDER 35 U.S.C. 102/103 CAN BE MADE WHEN THE PRIOR ART PRODUCT SEEMS TO BE IDENTICAL EXCEPT THAT THE
PRIOR ART IS SILENT AS TO AN INHERENT CHARACTERISTIC

Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. "There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102." *In re Best*, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims.

Claims 1, 9, 10, 12, 14, 15, 28, 47, and 48 are rejected under 35 U.S.C. 102(e) as being anticipated by Li et al [US 2002/0114784 A1].

Li et al disclose A method for attenuating the expression of a target gene in a cell comprising introducing into the cell a double stranded RNA in an amount sufficient to attenuate expression of the target gene, wherein the double stranded RNA comprises a nucleotide sequence that is essentially identical to the nucleotide sequence of at least a portion of the target gene [claim 1, for example]. The target gene can be endogenous or the target gene can be foreign [claims 2 and 3 and paragraph 32, for example]. The cell can be a mammalian cell including a human cell [claim 11 and paragraph 33, for example]. The double stranded RNA can comprise a sequence that is completely identical to the nucleotide sequence of at least a portion of the target gene [claim 15, for example]. The double stranded RNA can be formed from one strand to take the form of a self-complementary hairpin-type molecule that doubles back on itself to form a duplex [paragraph 36, for example]. The cells can be in culture [paragraph 6 and 44-46, for example]. The double stranded RNA can be delivered to cell via vectors [paragraphs 45 and 46, for example].

Li et al meet all of the structural limitations for the compounds required in the instant method claims. Any functional limitations such as being a substrate for RNAse III, not producing a general sequence independent killing in mammalian cells (PKR response) and inhibition by at least 5 fold are presumed by the examiner to be present in the structures disclosed by Li et al since they meet all of the structural requirements

of the claims. If applicant believes that there is/are specific structures that provide for these properties of the claimed method and are not disclosed by the prior art applicant should point to those structures of their claimed invention as they pertain to mammalian cells.

Applicant is reminded:

> **A REFERENCE TEACHING PRODUCT APPEARING TO BE SUBSTANTIALLY IDENTICAL IS MADE THE BASIS OF A REJECTION,
> AND THE EXAMINER PRESENTS EVIDENCE OR REASONING TENDING TO SHOW INHERENCY, THE BURDEN SHIFTS TO THE
> APPLICANT TO SHOW AN UNOBVIOUS DIFFERENCE**
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> **"[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency' under 35 U.S.C. 102, on prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. *In re Fitzgerald,* 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting *In re Best,* 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)).**
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U.S.C. 102." *In re Best*, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of**

function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 9, 10, 12, 14, 15, 28, 47, and 48 are rejected 35 U.S.C. 103(a) as being unpatentable over Graham [US 6,573,099 B2].

Graham discloses a method of delaying or repressing the expression of a target gene in an animal cell comprising transfecting the cell with a genetic construct wherein the construct comprises at least two copies of a structural gene sequence, wherein the gene sequence comprises a nucleotide sequence that is identical to at least a region of the target gene, and wherein the at least two copies of the structural gene are placed

operably under the control of a single promoter sequence which is operable in the cell, wherein at least one copy of the structural gene sequence is placed operably in the sense orientation under the control of the promoter and where at least one other structural gee sequence is placed operably in the antisense orientation under the control of the promoter [claims 3, 7-9 and 18, for example]. The target genes include endogenous as well as foreign genes [column 4, line 40- column 5, line 6, for example]. Preferably the multiple structural gene unit comprises two structural genes in a head to tail or tail to tail or head to head configuration as an inverted repeat or palindrome [column 11, lines 3-63, and Figures 14 and 15, and Example 3].

Graham et al do not specifically disclose inhibition in cells suspended in culture, mammalian, primate of human cells specifically. However the invention described by Graham et al is for the inhibition of targeted genes in an organism to defend against infection of viruses and also to treat disease. It would have been obvious to one in the art that mammalian, primate and human cells are clearly comprised in the scope of the teachings of Graham since the viruses targeted are bovine (BEV) and human (HIV-1). It clearly would have been obvious for one in the art to perform the inhibition methods in cells in culture before the use of the methods in cells in an organism such as a human since one in the art would have recognized the savings in cost and further since one in the art would clearly be required to test such methods in an appropriate cell and animal model before testing in a human, for example.

The invention as a whole would therefore have been *prime facie* obvious to one in the art at the time the invention was made.

Grahams teachings meet all of the structural limitations for the compounds required in the instant method claims. Any functional limitations such as being a substrate for RNAse III, not producing a general sequence independent killing in mammalian cells (PKR response) and inhibition by at least 5 fold are presumed by the examiner to be present in the structures disclosed by Graham et al since they meet all of the structural requirements of the claims. If applicant believes that there is/are specific structures that provide for these properties of the claimed method and are not disclosed by the prior art applicant should point to those structures of their claimed invention as they pertain to mammalian cells.

Applicant is reminded:

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15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R. McGarry whose telephone number is (571) 272-0761. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sean R McGarry
Primary Examiner
Art Unit 1635